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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,984	03/16/2001	Rolf Heitmeier		6257

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 09/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/808,984

Applicant(s)

HEITMEIER ET AL.

Examiner

Darwin P. Erez

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1 recites the limitation "the rate" in line 1. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 1 recites the limitation "the present active substance concentration" in lines 4, 9-10. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 1 recites the limitation "the active substance supply" in lines 6-7. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 1 recites the limitation "the rate (R)" in line 7. There is insufficient antecedent basis for this limitation in the claim.
7. Regarding claim 2, the word "means" is preceded by the word(s) "input" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

8. Claim 4 recites the limitation "the body function" in line 2. There is insufficient antecedent basis for this limitation in the claim.
9. Claim 4 recites the limitation "the anaesthetic level" in line 3. There is insufficient antecedent basis for this limitation in the claim.
10. Claim 4 recites the limitation "the physiological signal" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.
11. Claim 5 recites the limitation "the BIS controller" in line 1. There is insufficient antecedent basis for this limitation in the claim.
12. Claim 5 recites the limitation "the control deviation" in line 4. There is insufficient antecedent basis for this limitation in the claim.
13. Regarding claim 6, the word "means" is preceded by the word(s) "selection" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).
14. Claim 7 recites the limitation "the time behaviour" in line 1. There is insufficient antecedent basis for this limitation in the claim.
15. Claim 7 recites the limitation "the depth of anaesthesia" in line 3. There is insufficient antecedent basis for this limitation in the claim.
16. As set forth by claim 7, the use of the terminology and/or in line 3 renders the claim vague and indefinite. It is unclear as to what the Applicant's intends to claim, i.e., both the active substance concentration and the depth of anaesthesia or either the

active substance concentration or the depth of anaesthesia alone. Correction is required.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,094,235 to Westenskow et al.

19. **As to claim 1**, Westenskow teaches an anaesthetic controller **5** for influencing the rate of active substance supply to a patient's body to attain and maintain a desired anaesthetic state, the controller comprising a model computing portion **301** calculating a current value of the present active substance concentration in the patient's body on the basis of a patient model and taking into consideration former values of the active substance supply, and comprising a control portion changing the rate of the active substance as a function of the current value of the present active substance concentration such that the present active substance concentration is controlled to attain a target value (col. 2, lines 29-48; col. 7, line 14 – col. 8, line 14).

20. **As to claim 2**, Westenskow teaches a controller wherein the target value of the active substance concentration is adjustable on an input means (col. 2, lines 18-25).

21. **As to claim 3**, Westenskow teaches a controller wherein the target value is determined in a body function computing portion in dependence on measured body functions (col. 5, lines 26-30).
22. **As to claim 4**, Westenskow teaches a controller that receives the anaesthetic level from a sensor **106** and calculates the target value.
23. **As to claim 5**, Westenskow teaches a controller that receives a manual target value and calculates the concentration target value.
24. **As to claim 6**, Westenskow teaches a selection means **312** to allow selection between a user input target value and a calculated target value.
25. **As to claim 8**, Westenskow teaches a controller wherein an upper and a lower limit of the anesthesia level is specified (col. 7, lines 25-45).

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westenskow et al. and in view of US 5,806,513 to Tham et al.
28. **As to claim 7**, Westenskow teaches all the limitations of the claim except for a display device.

Tham teaches an anesthesia apparatus having a display **23** that provides information regarding the status of the apparatus.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the display device of Tham to the device of Westenskow because it provides clinicians information regarding the operation of the device.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Aaron Lewis can be reached on (703) 308-0716. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

dpe
September 23, 2002


GLENN K. DAWSON
PRIMARY EXAMINER